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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,382	06/11/2001	David Stoloff	J&J-0102/GYN-082	3839

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EXAMINER	
PHAM, HUNG Q	

ART UNIT	PAPER NUMBER
2168	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/879,382	STOLOFF ET AL.	
	Examiner	Art Unit	
	HUNG Q. PHAM	2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,15,16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Specification

New title of the invention is acknowledged.

Claim Objections

The objection of claims 5 and 10 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101

The rejection under 35 U.S.C. § 101 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

- The rejection of claims 1 and 15 under 35 U.S.C. § 112, first paragraph, has been withdrawn in view of the amendment.

- The applicant has not provided supportive evidences for the claims 6 and 20. The rejection of claims 6 and 20 under 35 U.S.C. § 112, first paragraph, is sustained.

- The rejection of claims 3, 5 and 7 under 35 U.S.C. § 112, second paragraph, has been withdrawn in view of the amendment.

Response to Arguments

Claim Rejections - 35 USC § 103

Applicant's arguments with respect to the rejection of claim 1 under 35 U.S.C. § 103 have been fully considered but they are not persuasive.

- As argued by applicant at pages 9 and 10:

> As explained during the August 3 interview, Page 9 of MedWatch states "Report Serious Adverse Events and Product Problems with All Medical Products to MedWatch." Thus MedWatch is designed to collect information about adverse events and problems associated with *existing products*. Claim 1 (as amended), on the other hand, recites "accepting on said web site a plurality of submissions indicative of medical needs *not addressed by available medical products*" (emphasis added) and is directed to, for example, the collection of information indicating the need for a product or service that may not currently exist. To further highlight the distinction, Applicants have amended the claim to recite "development of a *new* medical product" (emphasis added).
>
> ....
>
> The Examiner cites the Classen abstract and Col. 7 lines 10-12, which both describe a method for using product data to enhance the safety of an *existing* medical product. The examiner also cites Classen Col. 9 lines 10-34, which describes a method of analyzing the adverse events through the setting of thresholds to determine safe and commercially viable use of an *existing* product. Thus the threshold is set to indicate a problem with an existing product that may require corrective action. As explained during the August 3 interview, the cited passages do not disclose the analysis of submissions to select a submission indicating "a medical product related to the selected medical need *not addressed by available medical products*" (emphasis added) for "development of a *new* medical product" (emphasis added) as recited by the claim.

The examiner respectfully disagrees.

In response to applicant's argument that the Classen reference does not discloses the intended use limitation "***to select the submission indicative of the medical need not addressed by available medical products***", and "***for development of a new medical product related to the selected medical need not addressed by available medical products***", a recitation of the intended use of the claimed invention

must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Classen discloses a method for using product data to enhance the safety of a medical product (Classen, Abstract) by analyzing Adverse Event data from MedWatch (Classen, Col. 7 Lines 10-12). Classen further discloses ***plurality of submissions***, e.g., an Adverse Event corresponding to a product as discussed above with respect to the teaching of MedWatch could be risk/benefit ***analyzed*** and the purpose is ***to select the submission indicative of the medical need not addressed by available medical products***, e.g., adverse event threshold 1/1000 is established and if 2 occurrences are observed then the product is deemed unsafe or commercially impractical for use (Classen, Col. 9, Lines 10-24).

Additionally, as disclosed by Classen, user of systems include manufactures of medical products (Classen, Col. 10 Lines 34-36) and the systems are useful for creating products (Classen, Col. 10 Lines 42-44) based on newly discovered adverse event (Classen, Col. 10 Lines 55-57). Thus, the purpose of selecting an adverse event exceeds a predetermined threshold is ***for development of a new medical product related to the selected medical need not addressed by available medical products***.

In light of the foregoing arguments, the rejection of claim 1 under 35 U.S.C. § 103 is sustained.

- Claims 9 and 15 recite similar limitations to claim 1, and claims 2-7, 16 and 18-20 depend from claim 1, 9 and 15 and are thus unpatentable for at least the same reasons as discussed above with respect to claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As in claims 6 and 20, the claimed limitation, *an invention submission disclosure form is transmitted to the user that submitted the medical need not addressed by available medical products and the solution to the medical need not addressed by available medical products*, was not described in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 15, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedWatch [The FDA Medical Products Reporting Program] and Classen [USP 6,219,674 B1].

Regarding claims 1 and 15, MedWatch is a Medical Products Reporting Program hosted by FDA ***for collecting medical product information*** and ***medical need not addressed by available medical products*** (MedWatch, Page 2, the purpose of MedWatch is to monitor medical products by collecting reports), comprising:

providing a web site having information about medical products (MedWatch, Page 1);

accepting on said web site a plurality of submissions indicative of medical needs not addressed by available medical products relating to the medical products from a plurality of users (As indicated at Page 9 of MedWatch, Health Professionals as users can summit Adverse Events Report and Product Problems Report with all Medical Products to MedWatch on the web site. As defined at pages 11-14 of MedWatch, any undesirable experience associated with the use of a medical product in a patient or a concern about the quality, performance or safety of any medication or device could be reported, e.g., reporting a Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or reporting a complaint about foul odor coming from the product

when it open. The examples of reports indicate *submissions indicative of medical need not addressed by available medical products relating to the medical products*);

categorizing the plurality of submissions indicative of the medical needs not addressed by available medical products according to at least one primary topic (As indicated at Page 9 of MedWatch, a report, e.g., Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or a complaint about foul odor coming from the product when it open, as *submissions indicative of the medical needs not addressed by available medical products* is categorized under *primary topic*, e.g., Adverse Events or Product Problems).

The missing of MedWatch is the step of ***analyzing said plurality of submissions to select the submission indicative of the medical need not addressed by available medical products for development of a medical product related to the selected medical need not addressed by available medical products where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic***.

Classen discloses a method for using product data to enhance the safety of a medical product (Classen, Abstract) by analyzing Adverse Event data from MedWatch (Classen, Col. 7 Lines 10-12). Classen further discloses ***plurality of submissions***, e.g., an Adverse Event corresponding to a product as discussed above with respect to the teaching of MedWatch could be risk/benefit ***analyzed*** and the purpose is ***to select the submission indicative of the medical need not addressed by available medical products, where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic***, e.g., adverse event threshold 1/1000 is established and if 2 occurrences are observed then the product is deemed unsafe or commercially impractical for use (Classen, Col. 9, Lines 10-24).

Additionally, as disclosed by Classen, user of systems include manufactures of medical products (Classen, Col. 10 Lines 34-36) and the systems are useful for creating products (Classen, Col. 10 Lines 42-44) based on newly discovered adverse event (Classen, Col. 10

Lines 55-57). Thus, the purpose of selecting an adverse event exceeds a predetermined threshold is ***for development of a new medical product related to the selected medical need not addressed by available medical products***.

The method of analyzing the Adverse Events is necessary for MedWatch in order to analyze risk and benefit of a particular medical product with respect to newly Adverse Event.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include the technique of analyzing Adverse Events as taught by Classen into MedWatch method in order to enhance the effectiveness of post-marketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

Regarding claim 9, MedWatch is a Medical Products Reporting Program hosted by FDA ***for collecting medical product information*** (MedWatch, Page 2, the purpose of MedWatch is to monitor medical products by collecting reports), comprising:

a computer hosting a web site wherein the web site stores information about medical products (MedWatch, Page 1 is a *web site stores information about medical products*, the *computer* that *host* the web site of Page 1 is an inherited feature), ***information about the medical products being electronically searchable and browseable*** (*information about the medical product*s, e.g., Case Studies at Pages 19-21, is *searchable and browseable* via TABLE OF CONTENTS of Pages 17-18);

a network connection whereby web pages are delivered to a remote computer and input is accepted from the remote computer (Internet is *a network connection*, *whereby web pages* as in Pages 1 and 4 are *delivered to* a consumer a heath professional with *a remote computer*, and with a conventional browser, *input is accepted from the remote computer*), ***the network accepting a plurality of electronic submissions indicative of a medical need not addressed by available medical products for the medical products*** (As indicated at Page 9 of MedWatch, Health Professionals as *users* can *summit* Adverse Events

Report and Product Problems Report with all Medical Products to MedWatch on *the web site*. As defined at pages 11-14 of MedWatch, any undesirable experience associated with the use of a medical product in a patient or a concern about the quality, performance or safety of any medication or device could be reported, e.g., reporting a Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or reporting a complaint about foul odor coming from the product when it open. The examples of report indicate *a medical need not addressed by available medical products relating to the medical products*).

The missing of MedWatch is the claimed limitation, ***medical needs not addressed by available medical products related to the medical products may be determined for the development of a new medical product related to the medical need not addressed by available medical products***.

Classen discloses a method for using product data to enhance the safety of a medical product (Classen, Abstract) by analyzing Adverse Event data from MedWatch (Classen, Col. 7 Lines 10-12). Classen further discloses ***medical needs not addressed by available medical products related to the medical products***, e.g., an Adverse Event corresponding to a product as discussed above with respect to the teaching of MedWatch, could be risk/benefit ***determined***, e.g., adverse event threshold 1/1000 is established and if 2 occurrences are observed then the product is deemed unsafe or commercially impractical for use (Classen, Col. 9, Lines 10-24).

Additionally, as disclosed by Classen, user of systems include manufactures of medical products (Classen, Col. 10 Lines 34-36) and the systems are useful for creating products (Classen, Col. 10 Lines 42-44) based on newly discovered adverse event (Classen, Col. 10 Lines 55-57). Thus, the purpose of selecting an adverse event exceeds a predetermined threshold is ***for development of a new medical product related to the medical need not addressed by available medical products***.

The method of analyzing the Adverse Events is a must for MedWatch in order to analyze risk and benefit of a particular medical product with respect to newly Adverse Event.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include the technique of analyzing Adverse Events as taught by Classen into MedWatch method in order to enhance the effectiveness of post-marketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

Regarding claims 2 and 16, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further discloses ***the categorization is done performed by each said plurality of users electronically selecting a category*** (MedWatch, Page 7).

Regarding claim 3, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claim 1, MedWatch further discloses the step of ***filtering the medical need not addressed by available medical product submissions*** (MedWatch Page 19, three deaths from 50 reports are filtered).

Regarding claims 4 and 18, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further disclosed ***a gatekeeper such that the gatekeeper filters out input that relates to product complaints*** is provided (MedWatch Page 13, product complaint is filtered out for further investigation).

Regarding claims 5 and 19, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further discloses the step of ***providing a gatekeeper such that the gatekeeper filters out input that describes an medical need not addressed by available medical products and a solution to the medical need not addressed by available medical products*** (MedWatch Page 19, TEMAFLOXACIN is withdrawn from market based on the reports).

Regarding claims 6 and 20, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 5 and 19, MedWatch further discloses ***an invention submission disclosure form is transmitted to the user that submitted the medical need not addressed by available medical products and the solution to the medical need not addressed by available medical products*** (MedWatch, The Privacy Statement at Page 1 as *an invention submission disclosure form* is transmitted to the user using hyperlink).

Regarding claim 7, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1, MedWatch further discloses the step of ***providing a computer implemented medical products information web site in conjunction with the medical needs not addressed by available medical products input such that users can input medical needs not addressed by available medical products while obtaining medical products information*** (MedWatch, Pages 5 and 19).

Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedWatch [The FDA Medical Products Reporting Program] and Classen [USP 6,219,674 B1] and further in view of drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled].

Regarding claim 10, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claim 9, but does not teach ***a medical products purchasing database whereby a user can purchase medical products in conjunction with the submission of a medical need not addressed by available medical products submission***.

Drugstore is a web site for purchasing medical products and has a medical products purchasing database, and by including a hyperlink to Drugstore, Adverse Events can be submitted in conjunction with a medical product purchasing.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include a hyperlink to Drugstore in order to order a medical product online.

Regarding claim 21, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1, MedWatch and Classen does not explicitly discloses the step of ***providing a computer implemented medical products purchasing web site*** in conjunction with MedWatch such that ***a medical products ordering is processed*** during inputting Adverse Events.

Drugstore is a web site for purchasing medical products and by including a hyperlink to Drugstore, Adverse Events can be inputted during processing a medical product ordering.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include a hyperlink to Drugstore in order to order a medical product online.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUNG Q. PHAM whose telephone number is 571-272-4040. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIM T. VO can be reached on 571-272-3642. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Le. Pham

HUNG Q PHAM
Primary Examiner
Art Unit 2168

September 20, 2007